JAN - 4 2005

510(k) Summary K043146

Summary of Safety and Effectiveness for Horizon Medical Imaging

5.1 Demographic Information

5.1.1 Date Prepared

October 8, 2004

5.1.2 Submitter

McKesson Medical Imaging Company
130 – 10711 Cambie Road
Richmond, B.C.
Canada, V6X 3G5
Tel: 604-279-5422
Fax: 604-279-5468

5.1.3 Contact

Robert MacNeil P.Eng.
Manager, Quality and Regulatory Affairs

5.2 Device Name

5.2.1 Trade or Proprietary Name

Horizon Medical Imaging

5.2.2 Common Name

Horizon Medical Imaging

5.2.3 Classification Name

Picture Archiving and Communications System (per 21 CFR 892.2050).

5.3 Devices to which Substantial Equivalence is being Claimed

510(k) Number	Device Name	Manufacturer
K925965	Picture Archiving and Communication Systems	Advanced Light Imaging Technologies Inc. (now McKesson Medical Imaging Company)
K973959	O2 Workstation and/or PACSView software	Olicon Imaging Systems Inc. (now McKesson Medical Imaging Company)
K023557	Centricity PACS Plus	GE Medical Systems

Horizon Medical Imaging is based on the above identified FDA cleared PACS software of A.L.I. Technologies Inc and Olicon Imaging Systems inc (which A.L.I Technologies Inc acquired in June 1998). A.L.I Technologies Inc. became McKesson Medical Imaging Company in July 2002.

5.4 Device Description

5.4.1 Function

Horizon Medical Imaging is software which when installed and run on Microsoft Windows 2000 and XP operating systems on commercially available IBM PC compatible computers, hardware components and peripherals, forms a medical image and information management system that

receives, transmits, stores, retrieves, displays, prints and processes digital medical images, digital medical video, and associated medical information from various medical imaging systems.

Its core components are:

- High resolution color and grayscale workstations for primary diagnostic interpretation and secondary review of the medical images, video and related information.
- Standard workstations for performing administrative functions of the system
- Storage and archive devices and systems for short-term and long-term storage of system data
- Servers for managing the distribution of system data
- Network infrastructure components for providing the communication channels between the system's core components and the various medical imaging systems
- Diagnostic quality printers for producing hardcopy of medical images and related information.

5.4.2 Scientific Concept

Horizon Medical Imaging is not based upon particular scientific concepts.

5.4.3 Significant Physical and Performance Characteristics

Medical Image and Video Modalities Supported

- All DICOM 3.0 recognized modalities (specifically including mammographic images)

Significant Software Features

- User roles and levels of access to patient records and studies
- Studies/images management
- Patient information management
- Actions on studies (e.g. find, open, report, close)
- Images and videos displays to user defined display protocols
- Image manipulation (e.g. zoom, pan, rotate, flip, window, level, non-linear Look Up Tables)
- Image measurements (e.g. distance, area, angle, intensity)
- Annotations on images
- Receiving images
- Printing images
- Sending images
- Importing/Exporting images
- Storing and archiving studies and patient information
- Recording, playing, storing and retrieving audio clips
- Scanning hardcopy documents; displaying, storing and retrieving electronic versions
- Creating, displaying, storing, retrieving accessory information for studies (e.g. notes, diagrams)
- DICOM standard approved lossy compression algorithms and file formats (lossy compression not indicated for mammographic images)

Hardware Requirements

- Minimum hardware configuration required by Microsoft Windows 2000 and XP; and
- Minimum hardware configuration indicated by American College of Radiology (in technical standards on "Digital Image Data Management" and "Teleradiology") for the official diagnostic interpretation of images.
- Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 megapixel resolution and meets other technical specifications reviewed and accepted by FDA.
- Only hard copy devices specifically FDA cleared for printing diagnostic quality copies of medical images are indicated for the official diagnostic interpretation of hard copy medical images printed from Horizon Medical Imaging.

5.5 Statement of Intended Use

Horizon Medical Imaging is a medical image and information management system that is intended to receive, transmit, store, retrieve, display, print and process digital medical images, digital medical video, and associated medical information from various medical imaging systems.

The medical modalities of these medical imaging systems include, but are not limited to, all modalities supported by ACR/NEMA DICOM 3.0 (specifically including mammographic images).

Horizon Medical Imaging is intended to connect to a variety of storage systems and printers via DICOM and other computer industry standard interfaces and protocols.

Lossy compressed mammographic images and digitized film screen images must not be reviewed for primary image interpretations. Mammographic images may only be interpreted using an FDA approved monitor that offers at least 5 megapixel resolution and meets other technical specifications reviewed and approved by FDA. Horizon Medical Imaging will simply perform normal image manipulations for grayscale and image contrast on mammographic images and will not perform image processing on mammographic images.

Horizon Medical Imaging is indicated for use by trained medical professionals including, but not limited to, radiologists, physicians, and medical technologists. Horizon Medical Imaging is also indicated for use in soft-copy diagnostic interpretation of medical images and video by physicians trained in such practice (specifically including soft-copy diagnostic interpretation of mammographic images).

5.6 Comparison of Technological Characteristics

Horizon Medical Imaging maintains the functionality of the A.L.I. Technologies *Picture Archiving and Communication System* (K925965) and Olicon Imaging Systems *O2 Workstation and/or PACSView software* (K973959).

Horizon Medical Imaging adds the intended use of soft-copy official diagnostic interpretation of mammographic images, which is an intended use of the GE Medical Systems *Centricity PACS Plus*.

In conclusion, Horizon Medical Imaging is substantially equivalent to the GE Medical Systems Centricity PACS Plus for the intended use of soft-copy official diagnostic interpretation of mammographic images.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2005

McKesson Medical Imaging Company
% Mr. N. E. Devine, Jr.
Responsible Third Party Official
Entela, Inc.
3033 Madison Ave., SE
GRAND RAPIDS MI 49548

Re: K043146
Trade/Device Name: Horizon Medical Imaging
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: 90 LLZ
Dated: December 17, 2004
Received: December 20, 2004

Dear Mr. Devine:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K043146

Device Name: Horizon Medical Imaging

Indications For Use:

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Prescription Use ✓ ~~AND~~/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K043146